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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,351	03/19/2001	Sidney T. Smith	CRTS-5679 (1417A P 450)	3473
7590	12/11/2006			EXAMINER PASCUA, JES F
Baxter Healthcare Corporation Corporate Research & Technical Services One Baxter Parkway DF3-3E Deerfield, IL 60015			ART UNIT 3782	PAPER NUMBER

DATE MAILED: 12/11/2006

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/813,351  
Filing Date: March 19, 2001  
Appellant(s): SMITH ET AL.

MAILED  
DEC 11 2006  
GROUP 3700

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Ted J. Barthel  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed October 10, 2006 appealing from the Office action mailed March 29, 2006.

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**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,788,121	SASAKI et al.	08-1998
5,988,422	VALLOT	11-1999

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 2, 6, 7, 8, 12, 14, 15, 17, 18, 19, 22, 30, 31, 52, 53, 54 and 55 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,988,422 to Vallot (previously cited). See Figs. 1 and 2.

It is brought to applicant's attention that the angle defined between the longitudinal edges 19, 19' and the tapered edges 17, 17', 18, 18' in Fig. 2 of Vallot is shown as being in the range from about 135.01° to about 138°, as claimed. Moreover, applicant's affidavit, filed 03/11/2005, admits that Vallot discloses an "angle range of 120° -150° between the panel peripheral edge and the end segment tapered edge." See paragraph 6 of the 03/11/2005 affidavit. Having met applicant's claimed range of angles in claims 17 and 18, the end panels of Vallot are inherently capable of extending outwardly from the sleeve beyond an imaginary plane when in the unfolded position shown in Fig. 2.

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Claims 2, 6, 7, 8, 12, 14, 15, 17, 18, 19, 22, 23, 30, 31, 52, 53, 54, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot.

Vallot discloses the claimed invention, especially an angle range of 120° -150° between the panel peripheral edge and the end segment tapered edge, which overlaps applicant's claimed angle range of 135.01° to about 138° and specific angle 136°. However, Vallot does not disclose end panels extending outwardly beyond an imaginary place at the ends of the sleeve as a result of an angle range of 135.01° to about 138° and specific angle 136°. Through routine experimentation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an angle between the panel peripheral edge and the end segment tapered edge in Vallot with an angle range of 135.01° to about 138° or a specific angle 136°, in order to form the bag with end panels extending outwardly beyond an imaginary place at the ends of the sleeve. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 36, 37, 38, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422.

Vallot '422 discloses the claimed invention, especially all of the materials used to construct the Vallot '422 container and its accessories being "capable of withstanding exposure to radiation and other known sterilization techniques." See column 3, lines 46-50. However, Vallot does not disclose the port closure (i.e. "stopper") in sterile

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communication with the port (i.e. "chimneys 8"). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stopper of Vallot '422 in sterile communication with the port of the container since it was known in the art to maintain the contents of bio-pharmaceutical containers in a sterile condition.

Regarding claims 43 and 44, the large diameter tube connector 10, small diameter tube connector 11 or 90° elbow connector 13 meet the structure of applicant's "vent closure" to the same degree as claimed.

Regarding claim 37, Vallot '422 discloses the claimed invention except for the communication member (i.e. a tube connecting to large diameter tube connector 10, small diameter tube connector 11 or 90° elbow connector 13) being about 6 ft. to about 30 ft. long. It would have been an obvious matter of design choice to use a 6 ft. to 30 ft. tube for the communication member of Vallot '422, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 29 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallot '422 and Sasaki et al.

Vallot '422 discloses the claimed device except for the top side of the container having a plurality of spaced-apart hanger connection locations. Sasaki et al. discloses that it is known in the art to provide a plurality of spaced-apart hanger connection locations 14. It would have been obvious to one having ordinary skill in the art at the

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time the invention was made to provide the top side of the Vallot '422 container with the plurality of spaced-apart hanger connection locations of Sasaki et al., in order to permit the container to be suspended. Furthermore, the plurality of spaced-apart hanger connection locations 14 of Sasaki et al are shown as being positioned inward from an outer edge of the top side as claimed.

#### **(10) Response to Argument**

Appellant remarks on page 11 of the appeal brief that Vallot does not anticipate the claims because Vallot does not disclose an end segment of the container having the claimed "additional amount of material" permitting the end panel "to extend outwardly...beyond the imaginary plane when the container is filled." It is noted that in the claims, the "additional amount of material" is the result of an angle in the range from 135.01° to about 138° formed between at least one panel peripheral edge and a corresponding end segment tapered edge. Furthermore, it is the additional material that permits the end panel "to extend outwardly...beyond the imaginary plane when the container is filled". Vallot discloses the top and bottom and bottom walls of the container being formed by "K" welds comprising perpendicular weld 16 and inclined welds 17, 17', 18, 18', 31, 32 (column 7, lines 1-5). Vallot further discloses the inclined welds of the "K" weld having an angle in the range of 30° to 60° relative: 1) to the vertical axis of the container (column 3, lines 9-11) or 2) to the direction of movement of container film during manufacture (column 4, lines 32-37 and column 5, lines 53-57). The angle of the inclined welds translates into an angle between inclined welds 17, 17',

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18, 18' and welds 19, 19' in the range of 120° to 150°. Vallot's angle range of 120° to 150° clearly overlaps appellant's claimed angle range of 135.01° to about 138° used to form the "additional amount of material". Having met appellant's claimed angle range, the top and bottom ends of Vallot would be formed with an additional amount of material as claimed.

Appellant remarks on page 13 of the appeal brief that Vallot does not inherently disclose an end panel that extends beyond an imaginary plane. The claims on appeal recite "an additional amount of material which permits at least a portion of the end panel to extend outwardly from the sleeve beyond the imaginary plane when the container is filled". As discussed above, the angle range of 120° to 150° in Vallot meets appellant's claimed angle range of 135.01° to about 138° and thus, forms an additional amount of material in the top and bottom panels of the container. Therefore, the additional amount of material formed by the angle range in Vallot inherently permits at least a portion of the top or bottom panel to extend outwardly from the container beyond an imaginary plane when the container is filled. Regarding appellant's remark that the extended end panel must be described in the Vallot reference, it is noted that appellant's claims recite the extended end panel in functional terms (i.e. *when* the container is filled). There is no explicit recitation in the claims requiring appellant's container to be filled and an end panel extending outwardly. Appellant's a recitation with respect to the manner in which the claimed container is intended to be employed does not differentiate the claimed container from Vallot, which satisfies the claimed structural limitations of an angle range of 135.01° to about 138° to form an additional amount of material.

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Appellant argues that the container of Vallot cannot have an end panel that extends beyond an imaginary plane because Vallot discloses “the sachet deployed in three dimensions to conform exactly to the geometry of the bottom and sides of a rigid container in which it will be placed (“K” weld).” However, there is nothing in Vallot that discloses the bottom of the rigid container to be flat. Therefore, the angle range of 30° to 60° disclosed in Vallot would allow conforming the sachet within a rigid container whose bottom extends beyond an imaginary plane.

Appellant remark that the Vallot reference emphasizes that the container assume a parallelepiped-shaped container and therefore cannot have an end panel that extends beyond an imaginary plane. However, claim 1 of Vallot recites the sachet “assuming when filled a *substantially* parallelepiped shape” (emphasis added). The claim language “substantially parallelepiped shape”, when considered with Vallot’s disclosed angle range of 30° to 60°, encompasses an end panel of the sachet that would extend beyond an imaginary plane.

Appellant’s remark that “the skilled artisan would recognize that *Vallot’s* container does not include an end panel that extends beyond the imaginary plane” is opinion. Appellant’s reliance on the Smith and Hurst affidavits to support this remark is misplaced. Both affiants recognize that Vallot discloses an angle range of 30° to 60° to form the end panels of the container. However, neither affiant provide evidence to support their assertion that the Vallot container does not include or is incapable of providing an end panels that extends beyond an imaginary plane. Actually, the finite element analysis performed by one of the affiants, William S. Hurst, to represent Vallot’s

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upper angle limit of 150° (page 55 of the appeal brief and labeled "Container End Seal Angle Analysis Case 1 - 150 deg") shows the bottom end panel of the container as rounded. Affiant's evidence appears to support the Examiner's assertion that the angle range disclosed by Vallot would allow at least a portion of the end panel to extend outwardly from the sleeve beyond an imaginary plane when the container is filled.

Appellant argue, on page 14, paragraph 3 of the appeal brief that, Vallot fails to disclose the recited angle range of 135.01° to 138° with specific specificity because Vallot fails provide a specific example within the claimed range. MPEP 2131.03 does not require that a specific example be found in the reference to reject the claims, but rather requires a case by case determination as to anticipation.

Appellant remark, on page 14, paragraph 3a of the appeal brief, that Vallot fails to provide a single example within the claimed angle range of 135.01°-138° does not remove the fact that the range of angles taught by Vallot anticipate appellant's claims. "[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if one of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Furthermore, the Smith affidavit is insufficient to rebut the Examiner's *prima facie* case of obviousness based on overlapping ranges. The Smith affidavit fails to show that the particular angle range of 135.01° to about 138° and specific angle 136° are critical by showing that the claimed angle range and specific angle achieve unexpected results relative to the angle range disclosed by Vallot. "In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed

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range achieves unexpected results relative to the prior art range." In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Since appellant has failed to show evidence exists of unexpected results within the claimed narrow range of 135.01°-138°, the broad angle range of 120°-150° in Vallot meets the claimed narrow range with sufficient specificity.

The Hurst affidavit has been presented to support appellant's argument that Vallot fails to provide a specific example within the claimed range of 135.01°-138°. According to the Hurst affidavit, only four models of large volume fluid-filled flexible containers were prepared using finite element analysis. The four models appear to represent the high end and low end of the range of angles in Vallot and the high end and low end of the range of angles in applicant's claims. The Hurst affidavit goes on to explain the results of each model (e.g. shape of bag and the amount of wrinkling). The affidavit comes to the conclusion that the high end and low end models of the Vallot range of angles produces a shape or wrinkles that are undesirable and the high end and low end of the claimed range of angles provides a usable container with minimal wrinkling. Paragraph 5 of the Hurst affidavit does not precisely discuss how much more a flexible container with a 120° angle is unsupported compared to a flexible container with a range of 135.01° to about 138°. The Hurst affidavit also does not discuss the acceptable amount of the flexible container can be unsupported and how this acceptable amount was determined. Paragraph 6 of the Hurst affidavit does not precisely discuss how many more wrinkles occur in a flexible container with a 150° angle than a flexible container with a range of 135.01° to about 138°. The Hurst

affidavit also does not discuss the acceptable amount of wrinkling a flexible container can have and how this acceptable amount was determined. The testing and results in the Hurst affidavit neither take into account, nor discuss, angles just outside the angle range of 135.01° to about 138° (e.g., 135° and 138.01°). The absence of such information in the affidavit does not convince the Examiner that the claimed range of 135.01° to about 138° yields an unexpected bag shape with minimal wrinkling.

Appellant remarks, on page 15, paragraph 3b of the appeal brief, claimed angle range of 135.01°-138° yields unexpected results. Appellant's affidavits do not support this assertion. The Smith and Hurst affidavits admit that below a certain angle, large volume flexible containers are prone to undesirable rupturing and beyond a certain angle, the large volume flexible containers exhibited undesirable wrinkling within a support container. Since appellant was aware of these two undesirable conditions, another person having ordinary skill in the art of large volume flexible containers would have been aware of these two undesirable conditions as well. Therefore, through routine experimentation within the claimed angle range of Vallot, a person having ordinary skill in the art would be able to arrive at an optimum range of angles for Vallot to provide a large volume flexible container that does not rupture or wrinkle within the support container when filled. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

As discussed above, the testing and results in the Hurst affidavit neither take into account, nor discuss, angles just outside the angle range of 135.01° to about 138° (e.g.,

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135° and 138.01°). The absence of such information in the affidavit does not convince the Examiner that the claimed range of 135.01° to about 138° is neither critical nor yields an unexpected bag shape with minimal wrinkling.

Appellant's remark that Vallot fails to adequately address the problem of full support within the support container and the problems associated with wrinkling is not indicative of unexpected results. "The failure of the prior art to mention a problem may be due to the fact that in practice the problem is not a serious one or that a large number of satisfactory solutions is readily apparent." See *In re Gershon*, 372 F.2d 535, 152 USPQ 602 (CCPA 1967). "An allegation of solving an unsolved problem in the art is not evidence of non-obvious unless it is shown that widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem." See *In re Allen*, 139 USPQ 492, 495 (CCPA 1963).

Regarding appellant's final remarks that the rejection of claim 29 and 51 should be reversed because Sasaki et al. teaches away from appellant's recited 200L container, appellant fails to point out the explicit recitation in Sasaki et al. that the disclosed container cannot have volume of 200L or that such a volume was undesirable. Appellant's reliance on paragraph 3 of the Smith affidavit to support their remark is misplaced because the Smith affidavit fails to mention the Sasaki et al. reference at all.

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**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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Primary Examiner

Conferees:

  
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